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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/669,353	09/26/2000	David W. Pennington	1417Q P 279	4575

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EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 04/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/669,353

Applicant(s)

PENNINGTON ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on January 8, 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4,9-14 and 16-37 is/are rejected.
- 7) ☒ Claim(s) 5-8 and 15 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-4, 9-14, 16 and 18-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Duronio et al., 6,328,229.

Duronio et al. discloses the invention substantially as claimed. More specifically, Duronio et al. discloses a tubular component (distal end of 16); a spray tip assembly (12) attached to the tubing, the spray tip assembly comprising: a first mechanical breakup unit (26) having at least one feed port (see proximal end of 26) configured to direct a fluid into a first spin chamber and issue into a first exit port (55a), and a second mechanical breakup unit (28) positioned alongside the first mechanical breakup unit and having at least one feed port (see proximal end of 28) configured to direct a fluid into a second spin chamber and issue into a second exit port (55b), wherein the first and second exit ports extend through the external surface of the spray tip, see figures 5 and 6.

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As to claim 2, a first funneling portion (see 26 in Figure 5) adjacent the first spin chamber and having a sloped sidewall configured to direct the fluid issuing into the first exit port; and a second funneling portion as claimed are disclosed.

As to claim 3, the device is dimensioned to produce a spray from the exit ports and a force of a single magnitude is used to propel fluid as claimed, see column 4, line 58 – column 5, line 9.

As to claim 4, a first fluid source (16) in fluid communication via the tubular component with at least one first feed conduit and a second fluid source (18) as claimed, wherein the at least two conduits deliver fluid to different mechanical breakup units are disclosed.

As to claims 5-8, 12, 13 and 15, the spin chambers are located at (50 and 52), see Figure 5.

As to claims 9 and 10, the fluids are fibrinogen and thrombin, see column 1, lines 18-19.

As to claims 12 and 13, the device is capable of having a resulting spray cone of one of the fluids having a width greater than a resulting spray cone of the other fluid. (The spray cone of the fluids have different widths depending on the viscosity of the fluid and the velocity of the fluid being ejected.)

As to claim 14, feed ports (see proximal ends of 26 and 28) directing fluid from the feed conduits to the spin chamber of each mechanical breakup unit are disclosed.

As to claim 16, at least one additional conduit (see distal end of 26) is positioned through the spray unit assembly.

However Duronio et al. does not disclose that the spray tip assembly has a diameter of at most about 12 mm. Also, as to claims 18-37, Duronio et al. does not disclose specifically the rate at which the fluid exits the device, nor the diameter of the spin chambers, nor the angle of the sloped sidewall, nor the width of the feed ports, nor the height of the feed ports, nor the diameter of the exit port, nor the length of the exit port, nor the length of the exit port, nor the ratio of the diameter of the spin chamber to the diameter of the exit port, nor the ratio of the width of the feed port to the height of the feed port, nor the ratio of the length of the exit port to the diameter of the exit port, nor the ratio of the length of the spin chamber to the diameter of the exit port, nor the ratio of the exit port length to the exit port diameter, nor the diameter of the spray tip assembly, nor the diameter of the spray tip.

However, Duronio et al. discloses that varying the dimensions of the device may be made without deviating from the scope of the invention, see for example, column 4, lines 14-17, and column 5, lines 3-9, and lines 26-28 and lines 47-64, where Duronio discloses that having dimensions in certain ratios is preferable. It would have been obvious to provide a device as taught by Duronio et al. in the specific dimensions or ratios as claimed by Applicant, since such dimensions or ratios would not depart from the scope of the invention as taught by Duronio et al.

2. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Duronio et al., 6,328,229, in view of Sawhney et al., 6,121,341.

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Duronio et al. disclose the invention substantially as claimed, except for the additional conduit being an optical fiber.

Sawhney et al. discloses a device for dispensing a fluid to a tissue surface with two chambers for receiving fluids, and an optical fiber (106) to deliver light from a remote source for illumination during use of the device, see column 2, line 64 – column 3, line 7, and column 13, lines 37-56. It would have been obvious to combine Sawhney et al. with Duronio et al. since both disclose a device having two chambers for receiving fluids, the device being used for dispensing a fluid to a tissue surface. Specifically, it would have been obvious to provide an optical fiber as taught by Sawhney et al. in the Duronio et al. device, as it would be desirable for illumination of the treated site, as taught by Sawhney et al.

### ***Allowable Subject Matter***

3. Claims 5-8 and 15 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is a statement of reasons for the indication of allowable subject matter: the combination of elements including a device having a first and second mechanical breakup unit and at least two first feed conduits for delivering fluid in the first mechanical breakup unit and into a first exit port, and at least two second feed conduits for delivering fluid to the second mechanical breakup unit and into a second exit port,

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wherein the first and second exit ports extend through the external surface of the spray tip of the device, was not found in the prior art search.

### ***Response to Arguments***

Applicant's arguments filed January 8, 2004 have been fully considered but they are not persuasive. Applicant argues on page 13 that conduit (26) and conduit (28) in the Duronio device are not mechanical breakup units, or pressure swirl atomizers as defined by the Applicant in the application.

In response, Examiner asserts that Applicant has not positively recited structural limitations of the mechanical breakup units, or pressure swirl atomizers, which would distinguish the claims over the prior art, and do not otherwise distinguish over the prior art.

Applicant discloses that mechanical breakup units are known in the art as pressure swirl atomizers (specification, page 9, line 1). However, Applicant has not defined in Applicant's specification that the term mechanical breakup units as used by Applicant encompasses only pressure swirl atomizers.

In any case, elements (26 and 28) disclosed by Duronio are capable of allowing fluid to swirl (see figure 1 and figure 6) and to atomize to the extent that some fine particles of fluid will be produced. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In

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a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

As to Applicant's argument on page 14 that Sawhney fails to teach a first and second mechanical breakup units, Examiner asserts that Sawhney is relied upon only to modify Duronio to include an optical fiber, and that Duronio discloses the mechanical breakup units as described immediately above.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.




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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L. 

  
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04/05/04